Subchapter IX — Cabinet and Analytical X−ray Systems

HFS 157.87 Radiation safety requirements.

(1) GENERAL REQUIREMENTS. For certified cabinet x−ray systems including those designed to allow admittance of individuals, all of the following requirements apply:

(a) No registrant may permit any individual to operate a cabinet x−ray system until the individual has received a copy of and instruction in the operating procedures for the system. Records that demonstrate training compliance with this paragraph shall be maintained for department inspection until disposal is authorized by the department.

(b) Tests for proper operation of all interlocks shall be conducted and recorded at intervals not to exceed 12 months. Records of these tests shall be maintained for department inspection until disposal is authorized by the department.

(c) Compliance with dose limit requirements and radiation monitoring requirements of s. HFS 157.23 (1) (a) to (c) and 21 CFR 1020.40 shall be evaluated at intervals not to exceed one year. Records of these evaluations shall be maintained for department inspection for 3 years after the evaluation.

(d) A certified cabinet x−ray system shall be maintained in compliance with 21 CFR 1020.40. No modification may be made to the system without prior department approval.

Note: The title of 21 CFR 1020.40 is Cabinet X−ray Systems (39 Federal Register 12986, April 10, 1974).

(2) RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X−RAY SYSTEMS. The following safety equipment shall be used with all analytical x−ray systems except as otherwise noted:

(a) *Safety device.* An analytical x−ray system utilizing an open beam configuration shall incorporate a safety device that prevents any portion of an individual's body from entering the primary x−ray beam path or that causes the beam to be shut off upon entry into its path. The person in control at the facility may apply to the department for an exemption from the requirement for a safety device. The application shall include all the following information:

1. A description of the various safety devices that have been evaluated by the person in control.
2. The reason each device evaluated in subd. 1. cannot be used.
3. A description of the alternative safety methods available to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices. The department shall approve the alternate safety devices prior to their installation on the system.

(b) *Warning devices.* Open−beam configurations shall be provided with a readily discernible indication of either of the following:

1. An indication of whether the x−ray tube is on or off, if the primary beam is controlled in this manner.

Note: The x−ray tube status is located near the radiation source housing.

2. An indication of whether the shutter is open or closed, if the primary beam is controlled in this manner. Warning devices shall be labeled so that their purpose is easily identified.

Note: The shutter status is located near each port on the radiation source housing.

(c) *Ports.* Unused ports on radiation source housings shall be secured in the closed position in a manner that will prevent casual opening.

(d) *Labeling.* All analytical x−ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:

1. "CAUTION − HIGH INTENSITY X−RAY BEAM," or words having a similar intent, on an x−ray source housing.
2. "CAUTION RADIATION − THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED," or words having a similar intent, near any switch that energizes an x−ray tube if the radiation source is an x−ray tube.

(e) *Shutters.* On open−beam configurations installed after January 1, 1979, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

(f) *Warning lights.* An easily visible warning light labeled with the words "X−RAY ON," or words having a similar intent, shall be located as follows:

1. Near any switch that energizes an x−ray tube and illuminates only when the tube is energized.
2. In the case of a radioactive source, near any switch that opens a housing shutter and illuminates only when the shutter is open.

(g) *Radiation source housing.* An x−ray tube housing shall be so constructed that with all shutters closed the leakage radiation measured at a distance of 5 centimeters from its surface is not be capable of producing an air kerma in excess of 25 uSv (2.5 mrem) in one hour at any specified tube rating.

(h) *Generator cabinet.* An x−ray generator shall be contained within a protective cabinet which limits leakage radiation measured at a distance of 5 centimeters from its surface to no more than 2.5 uSv (2.5 mrem) in one hour.

(3) AREA REQUIREMENTS.

(a) *Radiation levels.* The local components of an analytical x−ray system shall be located and arranged and shall include sufficient shielding or access control so no radiation levels exist in any area surrounding the local component group that could result in a dose to any individual in excess of the dose limits in s. HFS 157.23 (1). For systems utilizing x−ray tubes, the permissible radiation levels shall be met at any specified tube rating.

(b) *Surveys.* To demonstrate compliance with par. (a), radiation surveys of an analytical x−ray system shall be performed according to all the following criteria:

1. Upon installation of the equipment.

2. Following any change in the initial arrangement, number or type of local components in the system.
3. Following any maintenance requiring the disassembly or removal of a local component in the system.
4. During the performance of maintenance and alignment procedures if the procedures require the presence of a primary x−ray beam when any local component in the system is disassembled or removed.
5. Any time a visual inspection of the local components in the system reveals an abnormal condition.
6. Whenever personnel monitoring devices show an increase of 50% over the previous monitoring period or the readings are approaching the limits of sub. (2) (g) or (h). Radiation survey measurements are not be required if a person in control demonstrates compliance with par. (a) in some other manner.

(c) *Posting.* Each area or room containing analytical x−ray equipment shall have at least one sign conspicuously posted bearing the radiation symbol and the words "CAUTION – X−RAY EQUIPMENT" or words having a similar intent.

(4) OPERATING REQUIREMENTS.

(a) *Procedures.* Operating procedures shall be written and available to all analytical x−ray equipment workers. No individual may operate analytical x−ray equipment in any manner other than that specified in the procedures unless the individual has obtained written approval of the person in control.

(b) *Bypassing.* No individual may intentionally bypass a safety device unless the individual has obtained the approval of the person in control. When a safety device has been bypassed, a readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING" or words having a similar intent shall be placed on the radiation source housing.

(5) PERSONNEL REQUIREMENTS.

(a) *Instruction.* No individual may operate or maintain analytical x−ray equipment unless the individual has received instruction in and demonstrated competence in all the following:
1. Identification of radiation hazards associated with use of the equipment.
2. Significance of the various radiation warning and safety devices incorporated into the equipment or the reasons the devices have not been installed on certain pieces of equipment and the extra precautions required in such cases.
3. Proper operating procedures for the equipment.
4. Symptoms of an acute localized exposure that may cause a radiation burn.
5. Proper procedures for reporting an actual or suspected exposure.

(b) *Personnel monitoring.* Finger or wrist dosimetry devices shall be provided to and used by any of the following individuals:
1. An analytical x−ray equipment worker using a system having an open−beam configuration and not equipped with a safety device.
2. Personnel maintaining analytical x−ray equipment if the maintenance procedures require the presence of a primary x−ray beam when any local component in the analytical x−ray system is disassembled or removed. Reported dose values may not be used for the purpose of determining compliance with s. HFS 157.22 unless the dose values are evaluated by a medical physicist.

(6) IMAGING DEVICES. Industrial uses of hand−held imaging intensification devices are exempt from the requirements of this subchapter if the air kerma 18 inches from the source of radiation to any individual does not exceed 25 uSv (2.5 mrem) per hour. A device that exceeds this limit shall meet the requirements of this subchapter and the licensing or registration requirements of subchs. II or VIII.

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